IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	Confirmation No.: 9392
Boyd et al.	
Application No.: 10/749,640	Examiner: Juliana Nancy Harvey
Filed: December 31, 2003	Group Art Unit: 4153
Title: Dynamic Spinal Stabilization System	

<u>DECLARATION UNDER 37 C.F.R. 1.131</u>

I , Lawrence M. Boyd, hereby state as follows:

1. I am a named inventor on pending application S.N. 10/749,640, entitled" Dynamic Spinal Stabilization System," which was filed on December 31, 2003.

2. Prior to November 7, 2003, I and the other named inventors conceived a method for dynamic stabilization of motion segments of the spine that included the steps of: (i) positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between two vertebrae; (ii) engaging bone anchors to at least two vertebrae; and (iii) coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection of the bone anchor between the stabilization element and the corresponding vertebra to which the at least one of the bone anchors is engaged, as defined in at least claim 36 of the above-identified pending application.

3. Prior to November 7, 2003, I and the other named inventors also conceived a method for dynamic stabilization of a motion segment of the spine including the steps of: (i) introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment; and (ii) coupling a dynamic stabilization system across the motion segment, the system including at least one bone

anchor that permits natural motion of the disc by deforming a portion of the bone anchor, as defined in at least claim 41 of the above-identified pending application.

4. Prior to November 7, 2003, a confidential invention disclosure document was prepared on behalf of the named inventors of the present application, which document is attached hereto as Exhibit A. This confidential invention disclosure document included drawings and written material that described the methods that the named inventors had conceived prior to November 7, 2003, as well as various devices used to implement the method. Exhibit A is a true and authentic copy of that confidential invention disclosure document, except that the dates and certain confidential notations have been redacted.

5. During the period from November 7, 2003, until the constructive reduction to practice of our invention on December 31, 2003, I and the other named inventors diligently pursued the constructive reduction to practice of the invention embodied in that application, including the methods described above. During the period from November 7, 2003, to December 31, 2003, the named inventors met to discuss alternative embodiments of the devices used to perform the conceived methods, conducted strength analysis of some of the devices used to perform the conceived methods and conducted a review of potential prior art. True and authentic copies of documents showing these activities are attached as Exhibit B, with the dates and certain confidential notations redacted.

6. During the period from November 7, 2003, until the constructive reduction to practice of our invention on December 31, 2003, I and other named inventors worked with outside counsel in the preparation of the present patent application. Drafts of the application from the outside counsel and our comments regarding the drafts were circulated by in-house counsel for the assignee of the present application, Spine Wave, Inc. The outside counsel worked diligently in preparing the initial and subsequent drafts of the application, including the final version that was filed on December 31, 2003.

7. I believe that all of the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application of any patent that may issue thereon

Lawrence M Boyd Date: 10/10/2008

Lawrence M. Boyd

SPINE WAVE, INC.

INVENTION DISCLOSURE FORM

(FOR PATENT PURPOSES ONLY)

Attach Additional Sheets as Necessary

Disclosure No.: SW005
Date:________

1. **INVENTOR NAME(S):**
Larry Boyd (Durham, NC)
Mark LoGuidice (SpineWave, Shelton, CT)
John Pafford (Memphis, TN)
Andy Carter (SpineWave, Shelton, CT)
Tom Wilson (SpineWave, Shelton, CT)
Tylor Lipschultz (SpineWave, Shelton, CT)

2. **DESCRIPTIVE TITLE OF THE INVENTION:**

Flexible Spinal Stabilization Elements

3. **DETAILED DESCRIPTION AND OPERATION OF THE INVENTION:**
(Attach the description necessary to facilitate a clear understanding of the invention, including all relevant drawings and notebook pages.)

Current spinal fixation is focused on rigid fixation elements (e.g., rods/plates) anchored to the vertebrae with screw fixation into the spinal pedicles. Rigid fixation combined with fusion (arthrodesis) has been standard treatment of severe degenerative disc disease, though the concept of restoring segmental spine motion (arthroplasty) has been of clinical interest for decades.

It is recognized in orthopaedics that arthroplasty offers advantages over arthrodesis in the areas of degenerative conditions of the hip and knee, for example. Devices are now available clinically for intradiscal arthroplasty, such as articulating discs and polymeric nucleus pulposus replacements. With the availability of these disc and nucleus replacement concepts, broad interest in means of providing for enhanced spinal stabilization, while allowing some degree of mobility, has grown.

The earliest efforts at creating mobile spinal segments focused on the replacement of all or part of the intervertebral disc. Efforts on developing non-rigid stabilization concepts, like ligaments, have led to work on devices that allow mobility of the spine without placement into the intradiscal space. A variety of "extradiscal arthroplasty" concepts are in clinical evaluation in Europe and the United States (see attached summary of these clinical concepts – Attachment A). As can be seen in Attachment

A, there are many potential advantages to these "soft stabilization" concepts, that limit rather than eliminate spine segment motion. It seems increasingly clear that there are patients that will benefit from restriction of their abnormal (pathological) motion patterns and restoration of more normal spinal motion and segment alignment.

The proposed concepts offer surgeons the ability to utilize elements commonly used for spinal fixation (screws, rods, hooks, connectors, etc.), while allowing for adjustment of spine segment mobility and segment posture. Attachments B, C, D and E demonstrate these various concepts for flexible stabilization of the spine.

Overall, there are four areas of invention by the authors listed above:

1. Flexible screw concept (detailed in Attachment B) –
2. Flexible collar connector (Attachment C, D1 and E)
3. Flexible bearing connector (Attachment D1 and D2)
4. Tissue ingrowth prevention collar (Attachment D3)
5. Cross-sectional geometry modifications to reduce the ~~axial~~ stiffness ~~and [illegible]~~ (Attachment E

4. STATE IN GENERAL TERMS THE PURPOSE AND/OR THE NOVEL FEATURES OF THE INVENTION:

Spinal fusion is recognized to have limitations in the treatment of disc degeneration, especially in the earlier stages of disc degeneration, where it may be unnecessary to eliminate motion and rigidly fix together the vertebral bodies. It is believed to be important for the treatment of disc degeneration to both allow for unloading of the degenerated disc, as well as to allow for controlled levels of segment mobility.

Cells of the intervertebral disc should respond favorably to reduced (but not eliminated) mechanical loading via deposition of extracellular matrix proteins (collagen, proteoglycan, fibronectin, etc.) into the disc space. Disc degeneration may involve a mechanically overloaded and hypermobile segment that can be repaired via reverse of the mechanically damaging load environment. For example, clinical experience with the Dynesys system appears to show clinical cases where the disc becomes increasingly hydrated over time (increased signal intensity on MRI) following treatment with the dynamic stabilizing device.

Spinal instability is a recognized feature of degenerative disc disease. The proposed flexible system will allow for spinal mobility, while reducing the excessive instability associated with degenerative disc disease.

The truly novel aspect of this invention involves the incorportation of flexible elements at the individual spinal segments, rather than flexible elements spanning between segments. Surgeons will utilize elements commonly used for fusion, with the ability to incorporate flexibility within the screw or screw/rod or screw/plate connections. It should be possible to convert to a solid structure simply be replacing the flexible elements with more rigid or completely rigid elements. Additionally,

depending on the means by which flexibility is incorporated into the elements, it should be possible to directionally tailor the flexibility. For example, by tapering the screw it should be possible to allow for preferred flexion-extension mobility while significantly reducing rotational spinal mobility.

a screw with a non circular cross-section - tapered could be circular

5. HOW DOES THE INVENTION DIFFER FROM THE PRIOR ART AND STATE ITS ADVANTAGES:

Prior concepts for "extradiscal arthroplasty" primarily involve means of introducing flexible elements between spinal motion segments via flexible bumpers or elastic elements (see Attachment A). The concepts proposed in this disclosure introduce the flexible elements at the individual spinal element (vertebral body). Additionally, prior art concepts do not appear capable of altering the stiffness of the segment in various loading modes (e.g., flexion/extension, compression, lateral bending, axial rotation), as can be achieved with various alternatives proposed here via alteration of screw or connector geometry. Finally, it should be a simple matter to convert the flexible system to a more rigid or completely rigid system by replacing the interposing elements at a subsequent surgical procedure without needing to remove well-fixed pedicle screws, rather using these screws as anchor points for a revision procedure and a more-rigid constuct assembly.

6. IDENTIFY THE KNOWN PRIOR ART (PATENTS, PUBLISHED APPLICATIONS, PUBLICATIONS, ARTICLES, PRODUCTS, ETC.):

Attachment A summarizes many of the current concepts for "extradiscal arthroplasty". In general, these systems fall into two categories – 1. Interspinous process-based fixation and stabilization and 2. Pedicle screw-based fixation and stabilization.

In addition to the information provided in Attachment A, a list of references is attached. Copies of these can be provided as needed.

7. COMPLETE THE FOLLOWING:

(a) Date of conception of the invention and where date is documented:
Conversation between Mark LoGuidice and Larry Boyd following presentation by Larry Boyd in Shelton, CT on

(b) Date the invention was first constructed, if any
Detailed conceptual drawings (Attachment B) sent to John Pafford and Bob Rodrick via email on

Additional concepts discussed and disclosed on in Shelton, CT during meeting. See Attachment D for these concepts.

Prototypes have not yet been constructed.

(c) Date of first test, if any:

(d) Has the invention been disclosed or used outside of Spine Wave, Inc. without a Confidentiality Agreement?
Yes ☐; No X
If yes, please provide details (i.e., when, where and to whom):

(e) Has the invention been sold or offered for sale? No

(f) Is commercial use or sale of the invention planned?

Commercial sale is likely, but extensive testing is first required.

If so, when?

Laurence M Boyd
Inventor Signature Date

Inventor Signature Date

Inventor Signature Date

Inventor Signature Date

Inventor Signature Date

INVENTOR SIGNATURE DATE

Read, Witnessed and Understood by:

Richard J Mang
Witness Signature Date

Witness Signature Date

FOR COMPLETION BY MANAGEMENT

Disclosure reviewed and approved by: Robert M. Rodrick
~~Manager~~ CHIEF PATENT COUNSEL
Date:______________

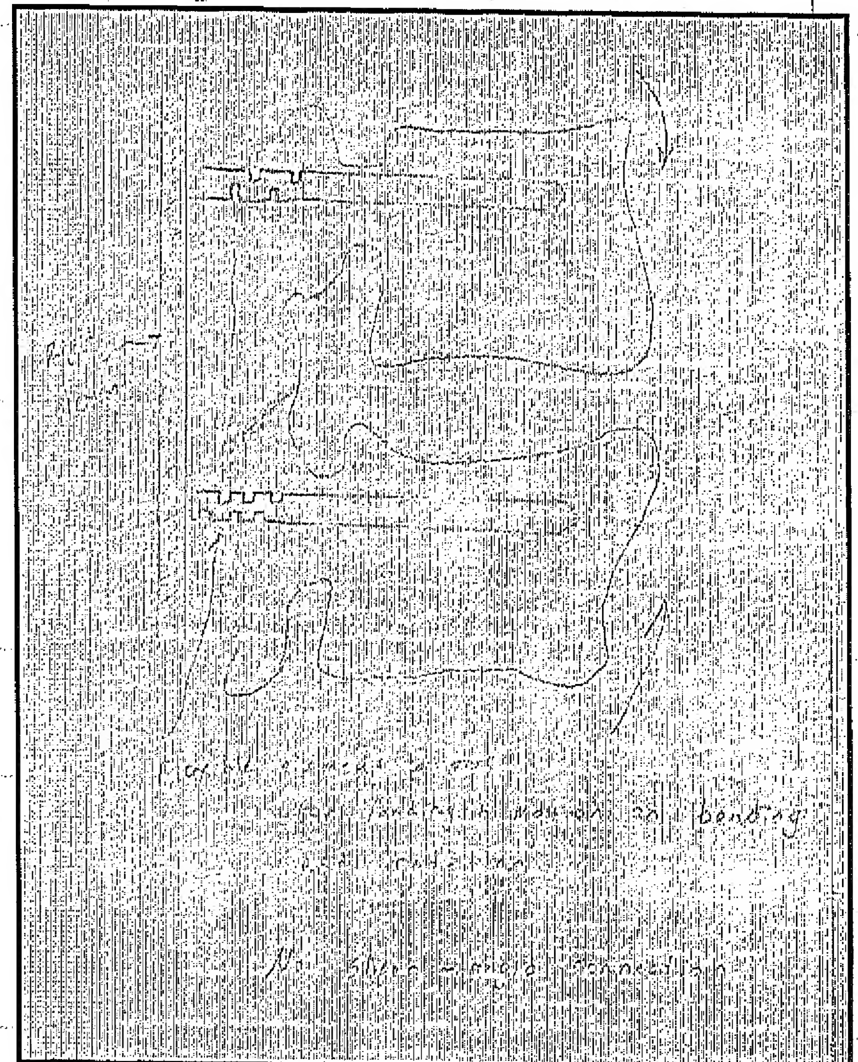
Request for patent filing reviewed and *accepted*: J. Pafford (John Pafford)
Date:______________

Request for patent filing reviewed and *declined*:__________________ (John Pafford)
Date:______________

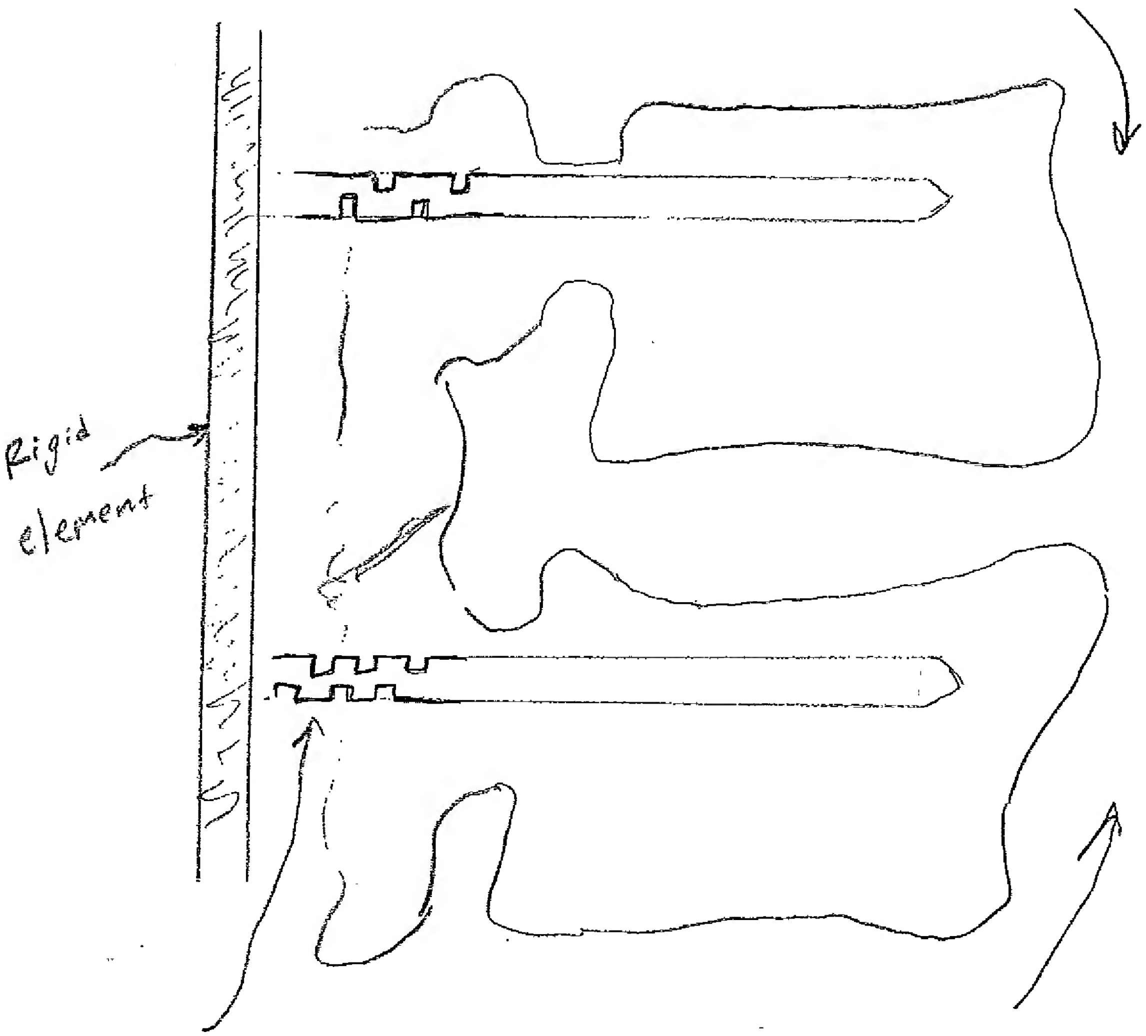
Request for Patent Filing approved: M. LoGuidice (Mark LoGuidice)
Date:______________

Flexible Screw Concept

- Focus on adding flexibility to the pedicle screw element
- Flexibility can be in one or multiple planes depending on how the cut-outs are oriented
- Alternatively, screws or elastomeric bumper elements can be used



B2



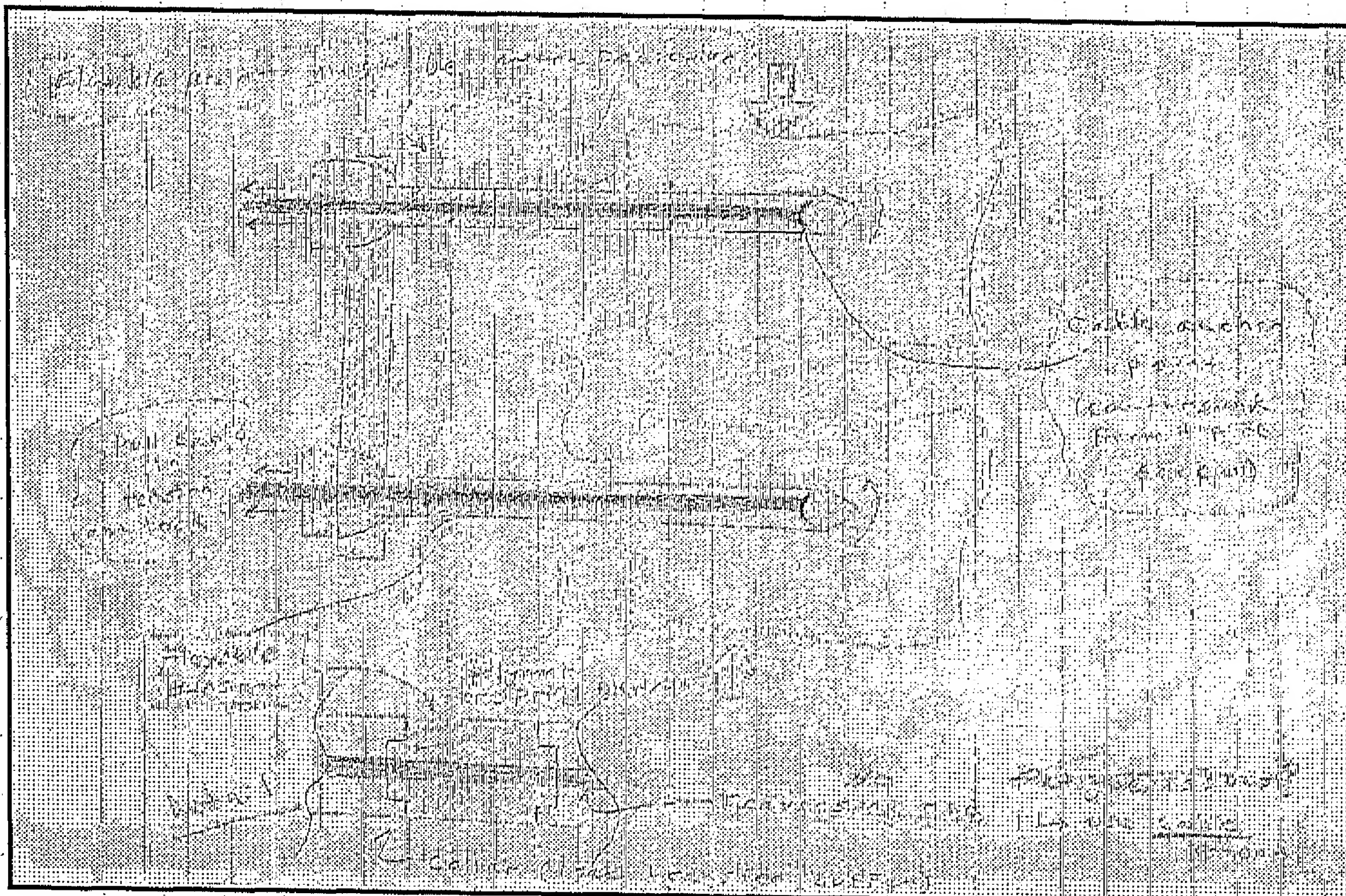
Flexible element allows
for loading + motion on bending
and rotation

No shear - rigid connection

L.M. Boyd

Flexible Screw Concept

- One concept – utilize an flexible element (spring, elastomer, etc.) and cable arrangement to hold in tension



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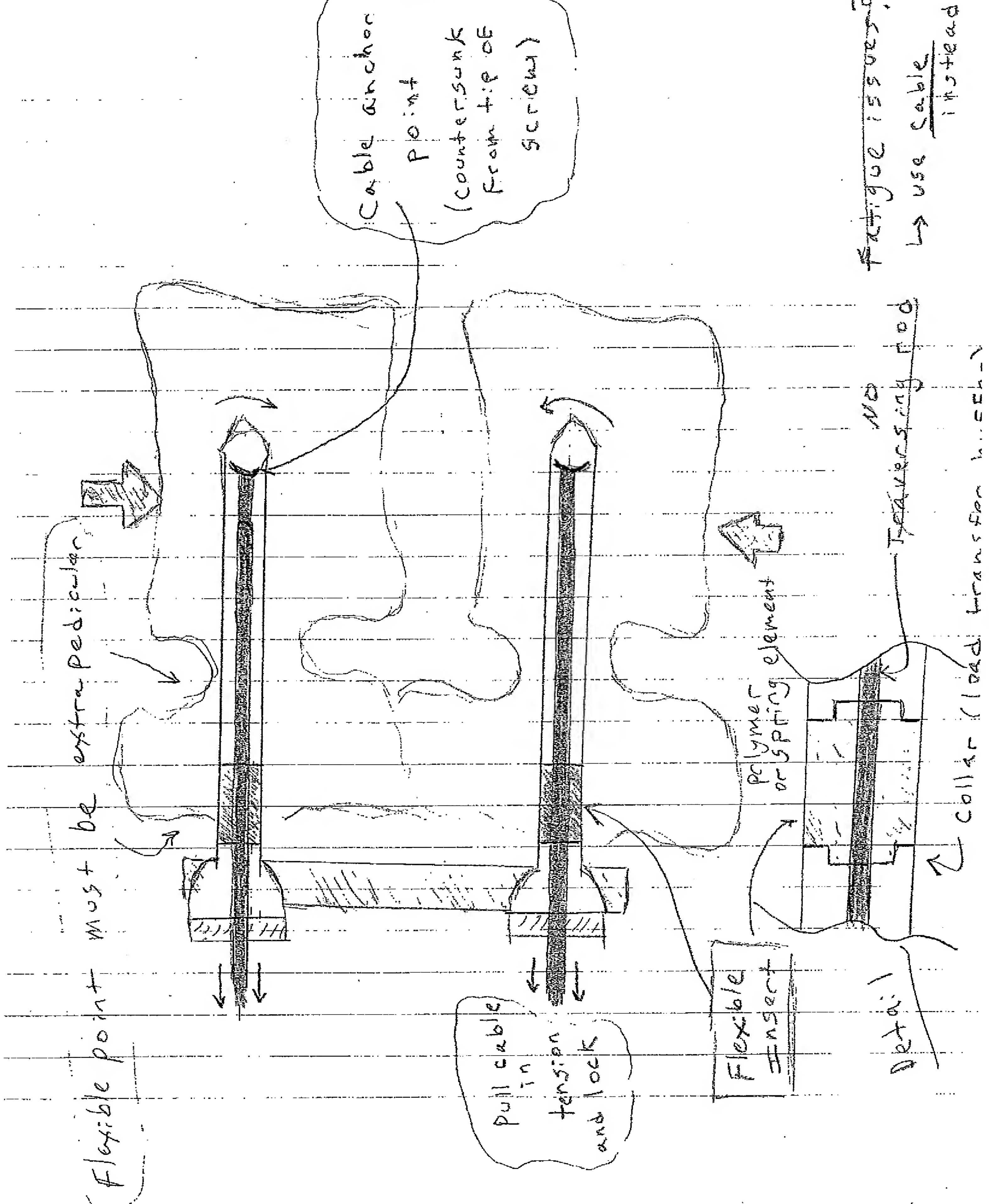
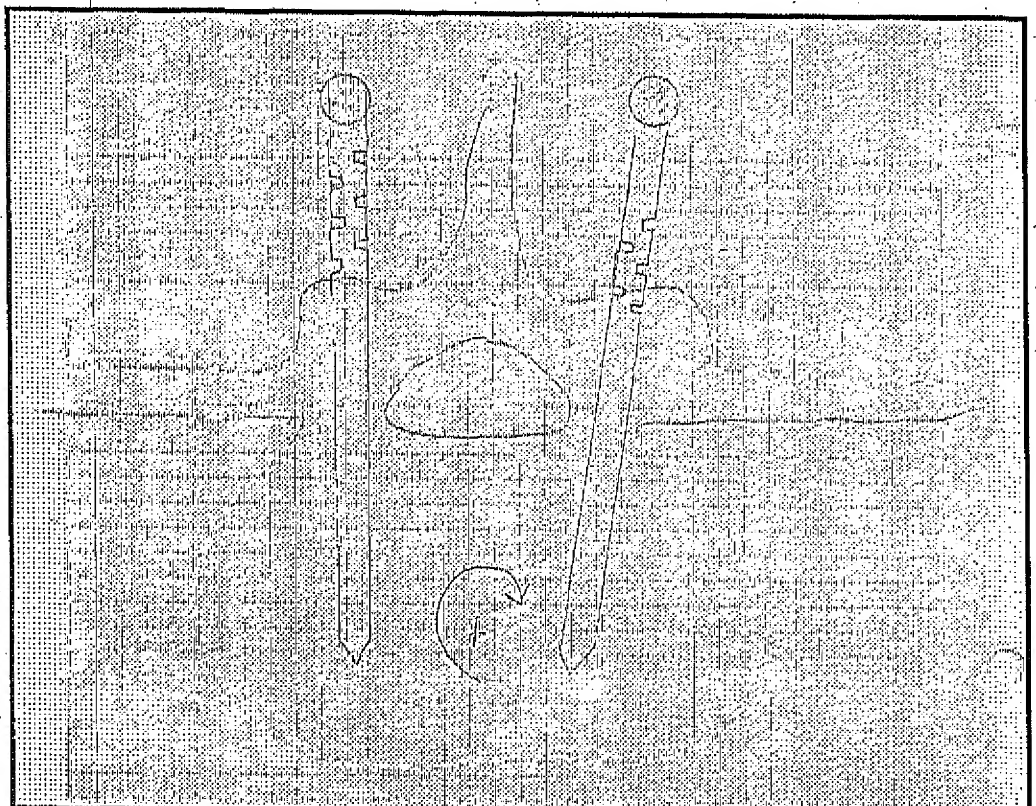

Cable anchor point (countersunk from tip of screw)
Flexible point must be extra pedicular
Pull cable in tension and lock
Flexible Insert
Polymer or spring element
Detail
Collar (load transfer
NO Traversing rod
Fatigue issues?
use cable instead

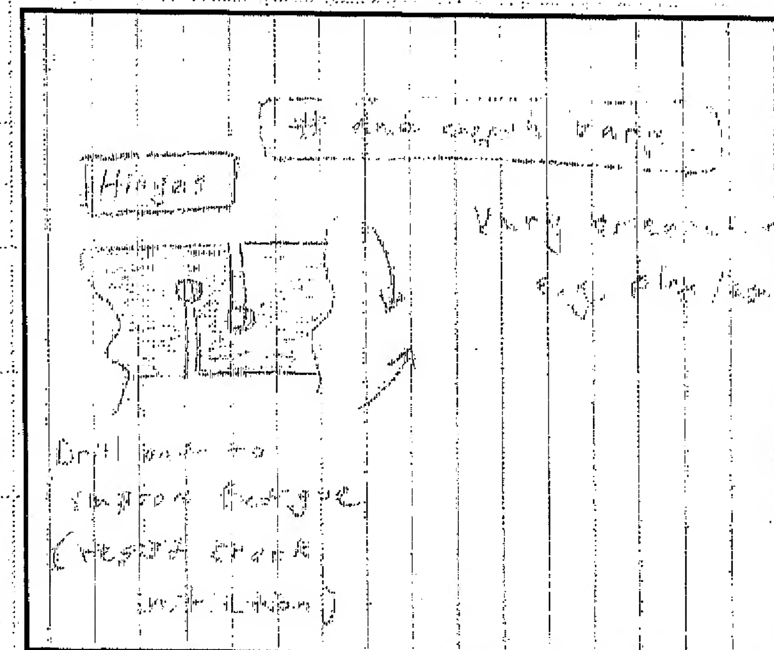
L. M. Boyd

B6

Flexible Screw Concept

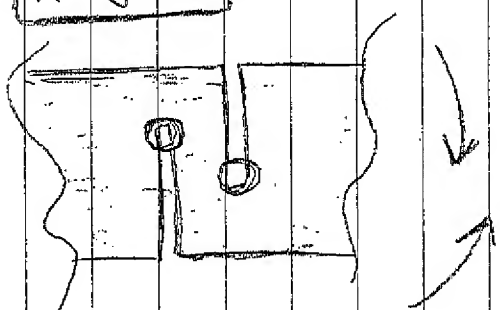
- Flexibility may be via various elements. One could be a series of cuts (with relief) that control amount and orientation of flexibility





and depth vary

Hinges



Vary orientation
e.g. flex/ext vs. rotation

Drill out to
improve fatigue
(resist crack
initiation)

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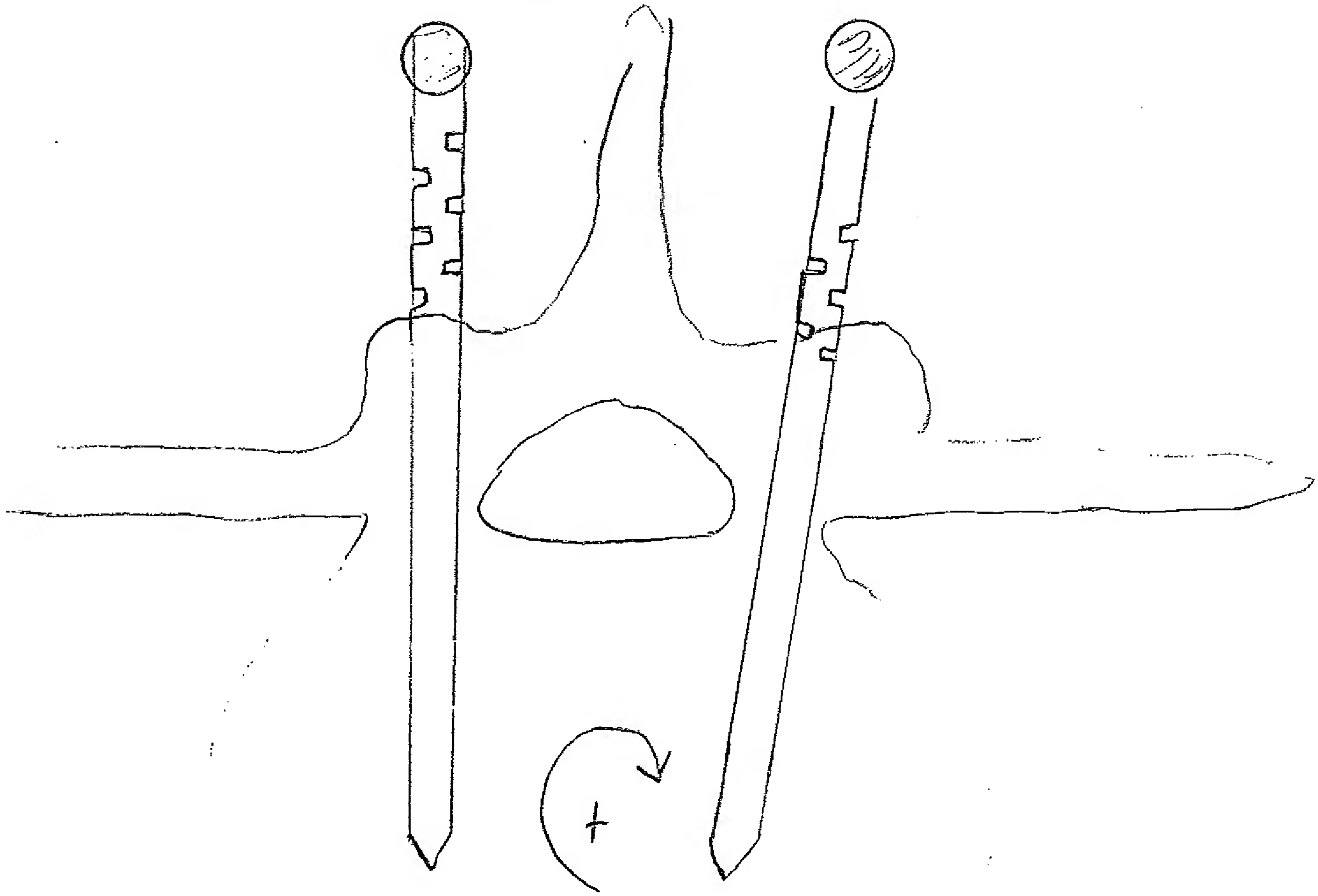
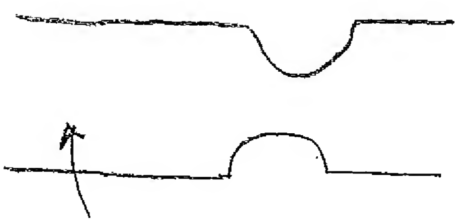
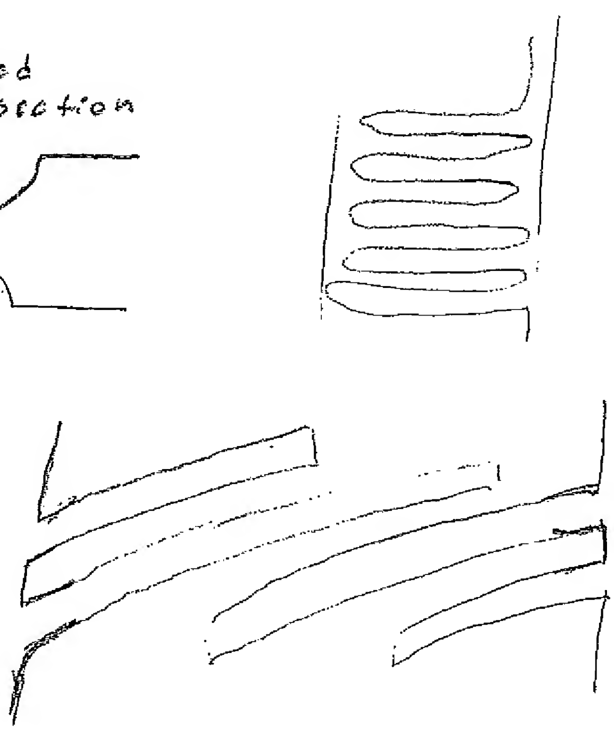
Exhibit A

BB



Reduced
X-section



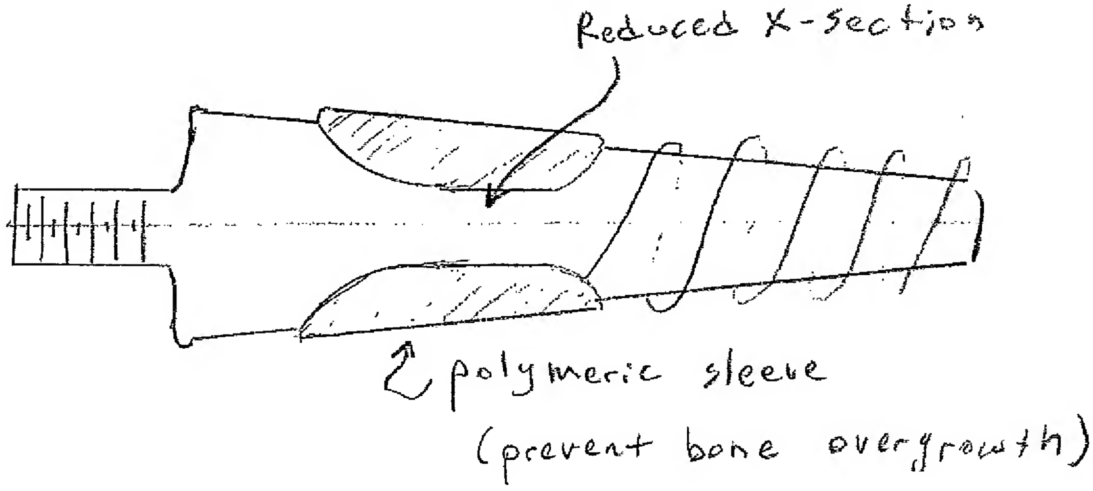


Spring
elements

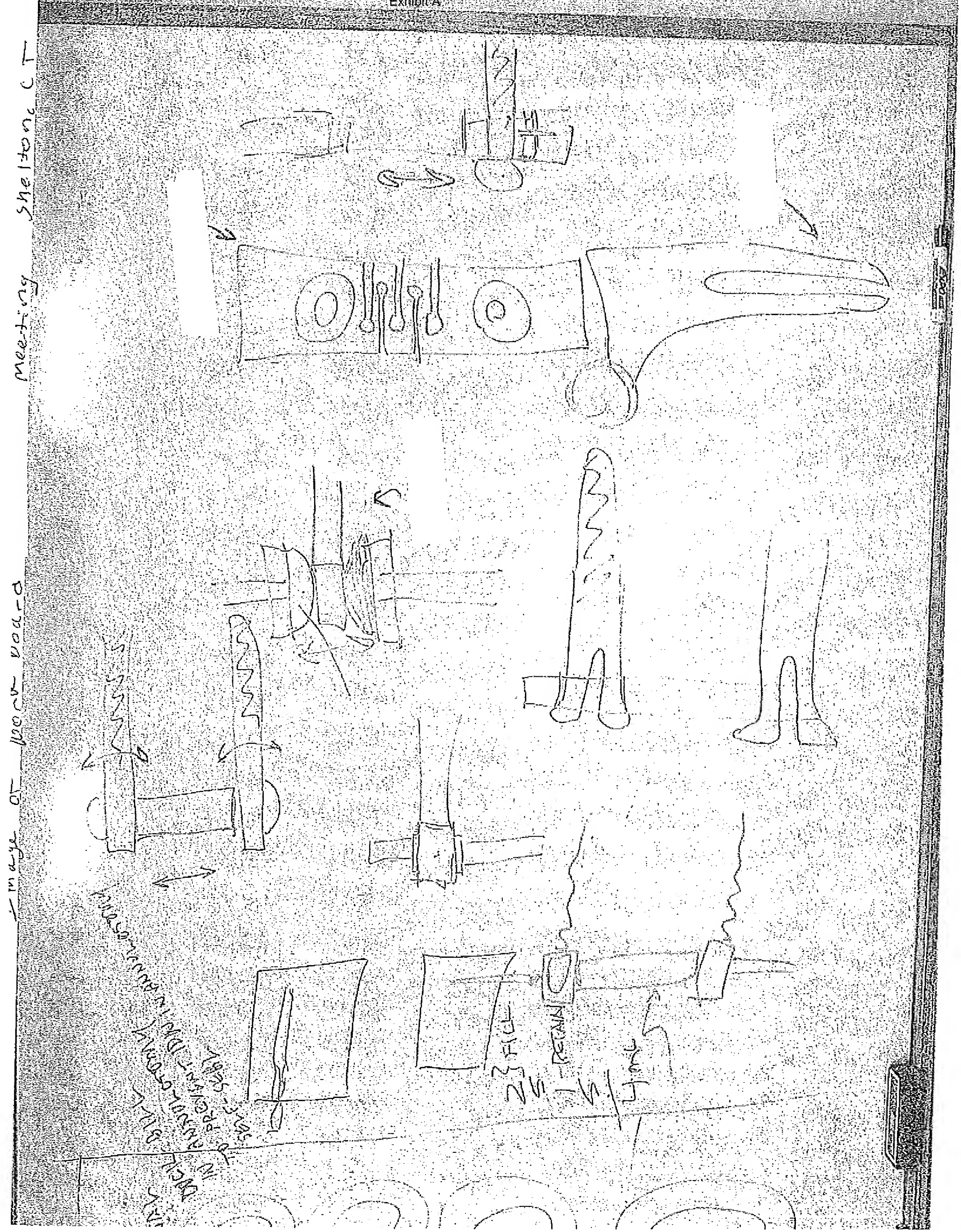
L. Boyd

Attachment D3

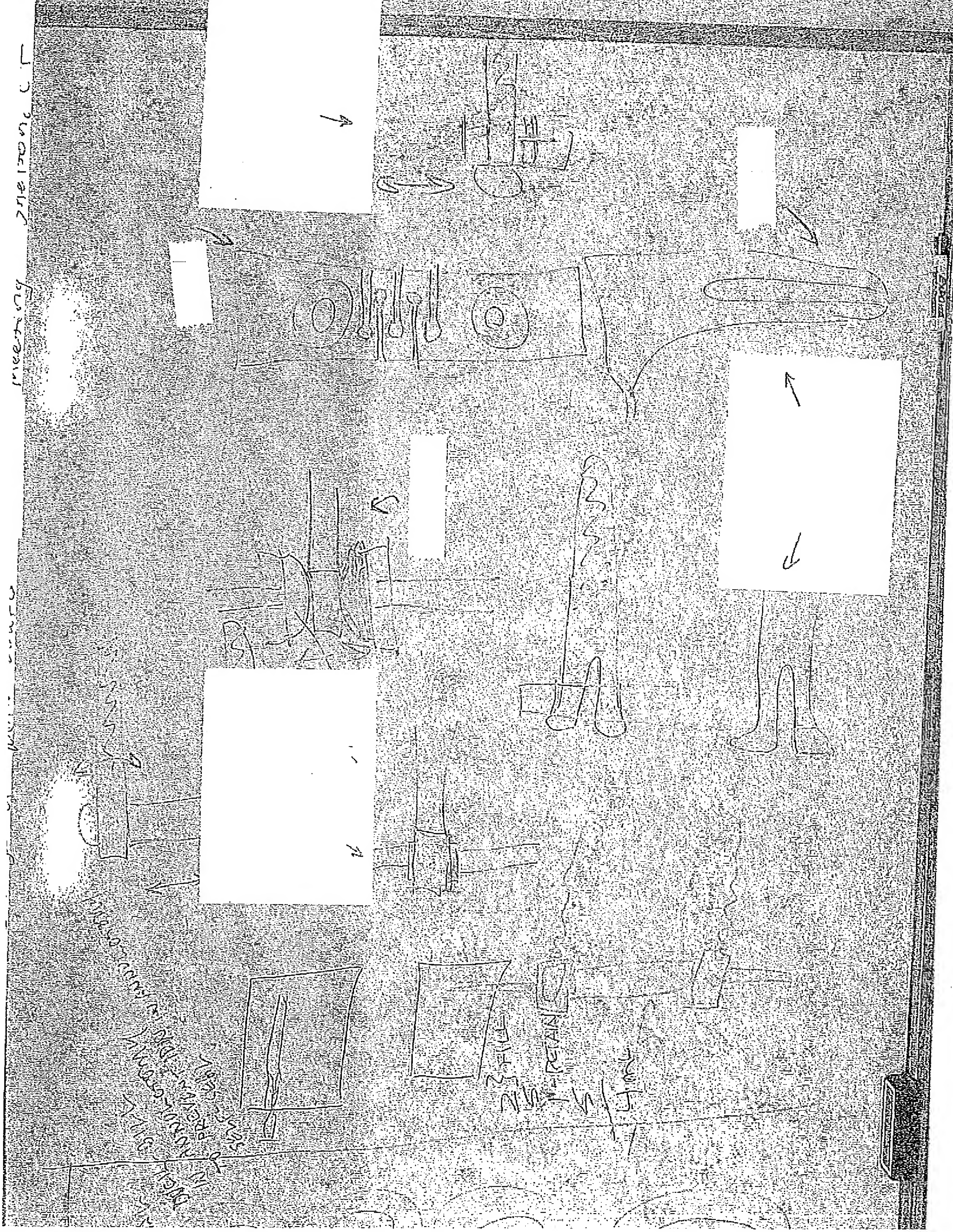
Reduced Cross-section Screw + Protective Sleeve



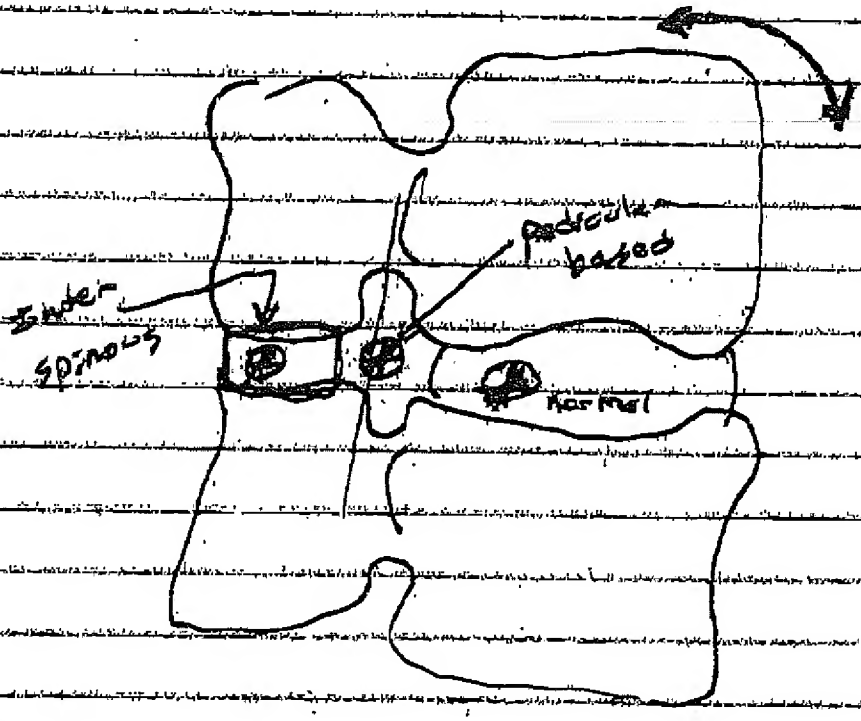
App. S.N. 10/749,640 Attachment E
Declaration Under 37 C.F.R. 1.131
Exhibit A



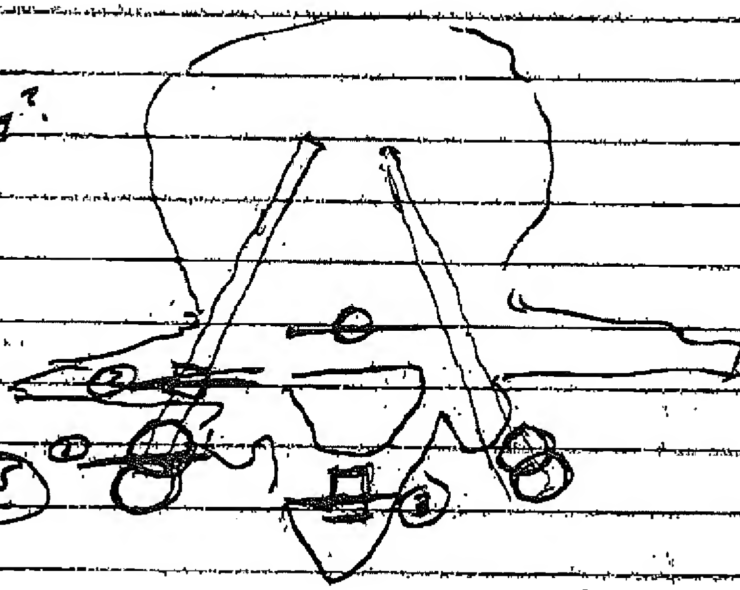
Attachment E



Center of rotation critical



Interspinous
- Kyphotic inducing?
- Distant Center of Rotation



Motion location?
① Dynesys
vs
② Flex Screw (closer? vs. rod location)
vs
③ DIAM furthest

→ Make entire screw flexble?
- material (PLA?) resorb late
- Cross section flexible over entire length or smaller

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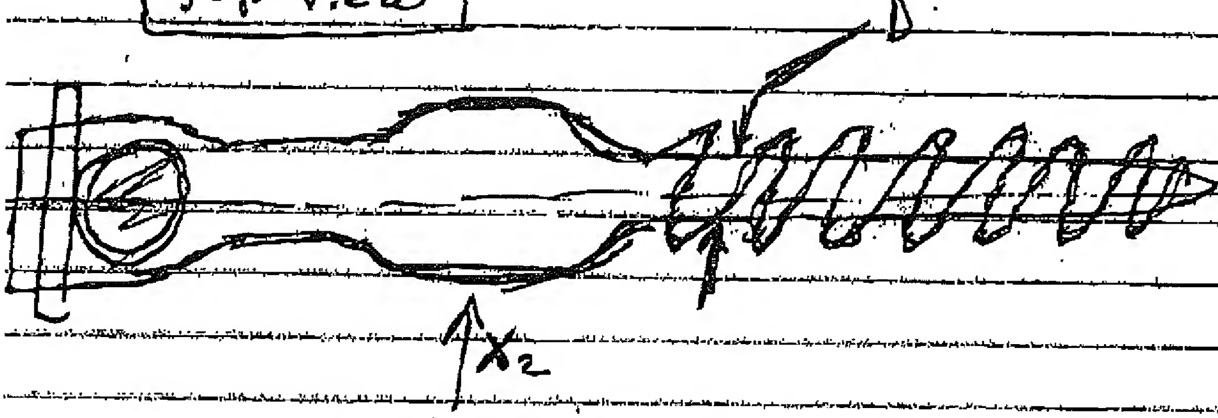
Exhibit B

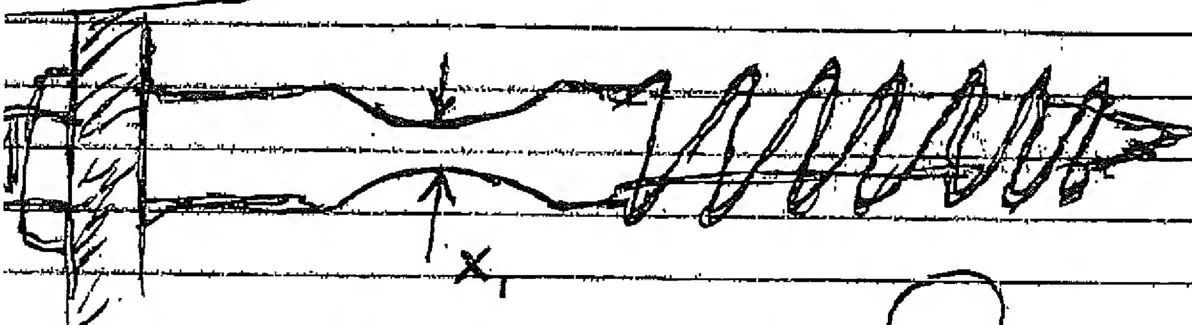
One potential solution - maintain cross-sectional area over screw length.

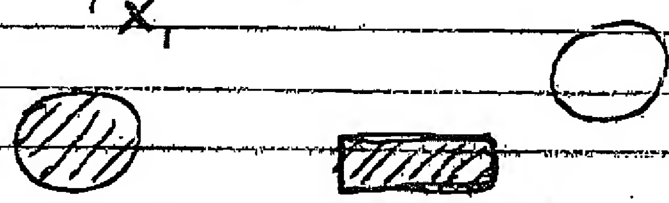
Top View



Add material volume to increase Fatigue resistance and assure Flex point is extra pedicular

Side View





$$A = \pi \left(\frac{D}{2}\right)^2 = X_1 X_2$$

Fixed varies along L

Add X section to compensate for stress intensity Factor, K_{tc}

510(k) possible - uniform material

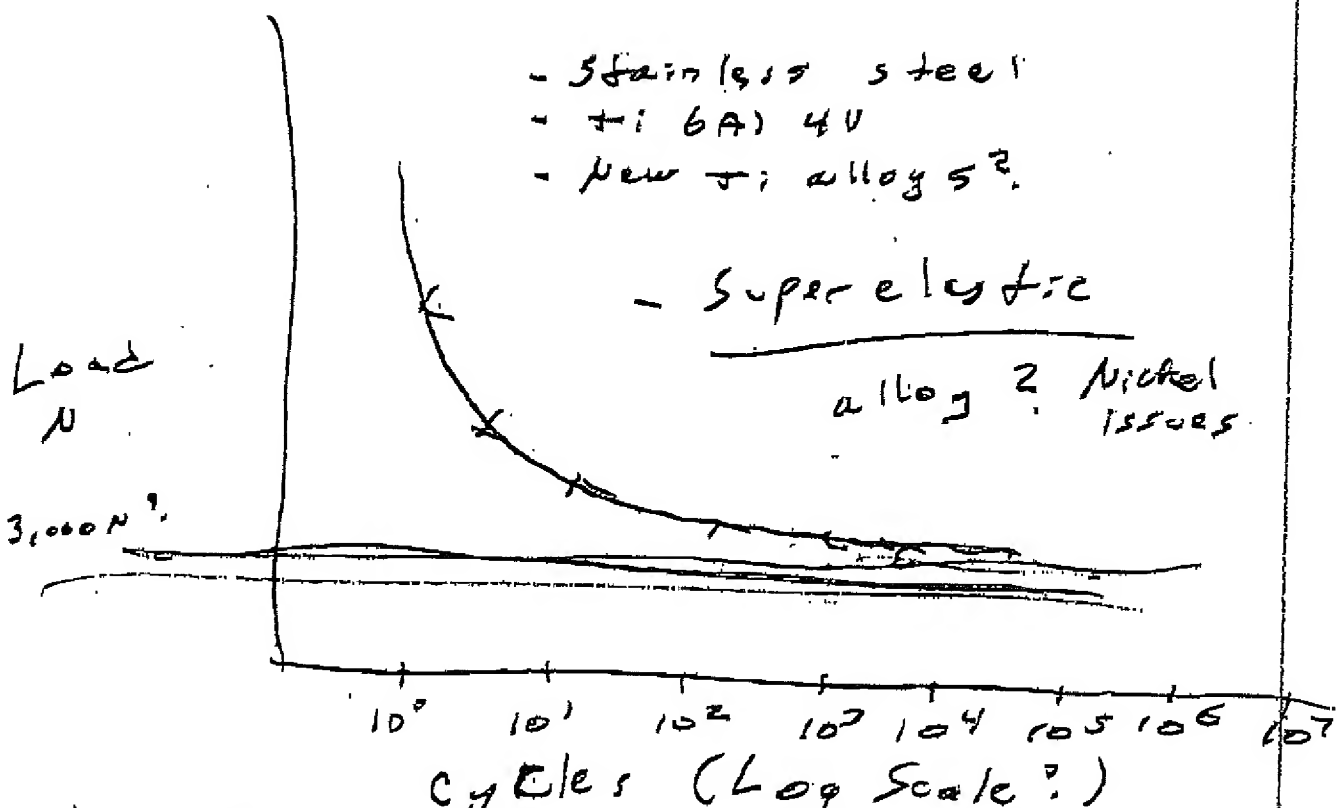
Jim Boyle

3

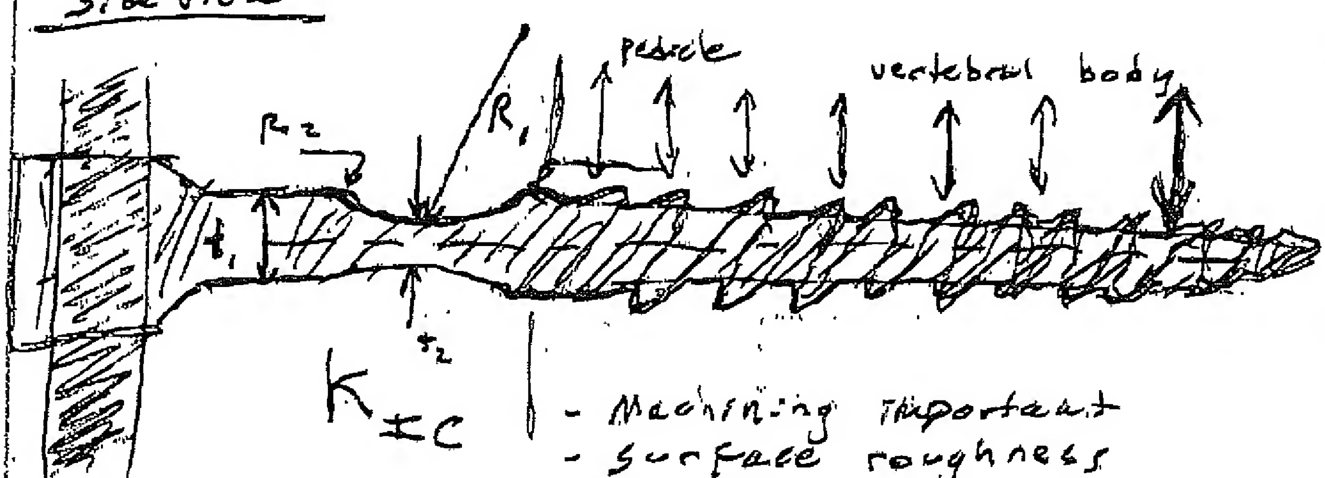
not fully reversed (tension-tension)

Fatigue Limit -

Check Fx + fatigue ~~text~~



Side view



K_{IC}

- Machining important
- surface roughness
- surface treatment
- polymer collar ~~to~~ prevent bone overgrowth

Add discussion of fatigue improvements (Attach E)

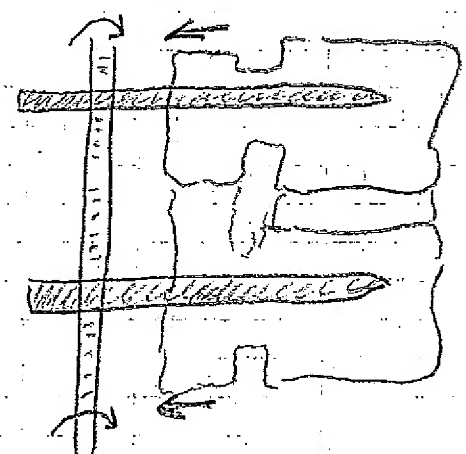
1.) Via material - polymers, composites, superelastic alloys (e.g. Nitinol)

2.) Via design - optimize radii, minimize stress concentration factors (e.g. Modified screw design Attach F)

3.) Via manufacture - minimize surface roughness, pretreat surface (e.g., Ti nitride, chrome), prestress surface (shot peen, etc.)

Advantage of use of rigid rod for deformity correction in scoliosis, spondylolisthesis, etc.

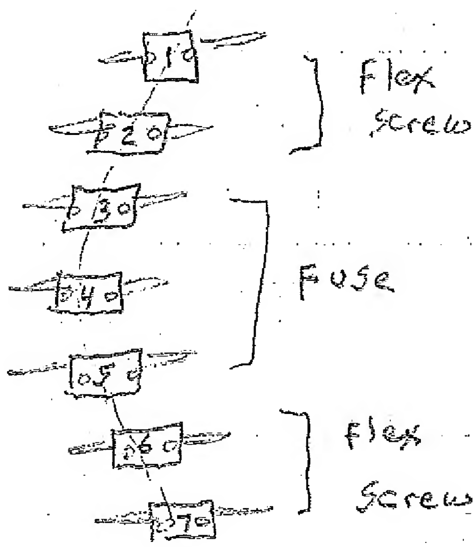
1.) Scoliosis - correction via rod rotation involves pulling vertebrae up to rod (this is not possible with a cable-based flexible system) Attachment G



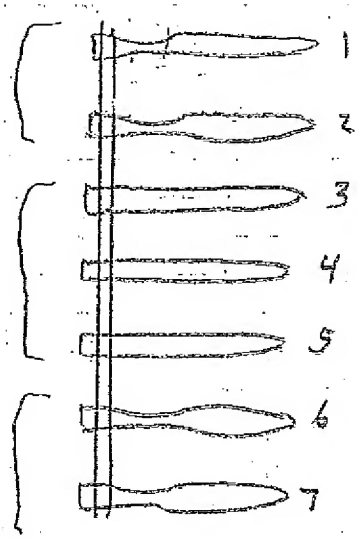
During rotation, rod reduction brings vertebrae up to rod.

Rigid (Fixed)

Use of a flexible system may be an advantage in scoliosis, where long rigid constructs may lead to accelerated degeneration at the distal ends (transition syndrome). It could be preferred to either use a completely non-fusion flexible screw + rod construct or to only fuse the middle segments to allow a flexible interface at the transitional segments.

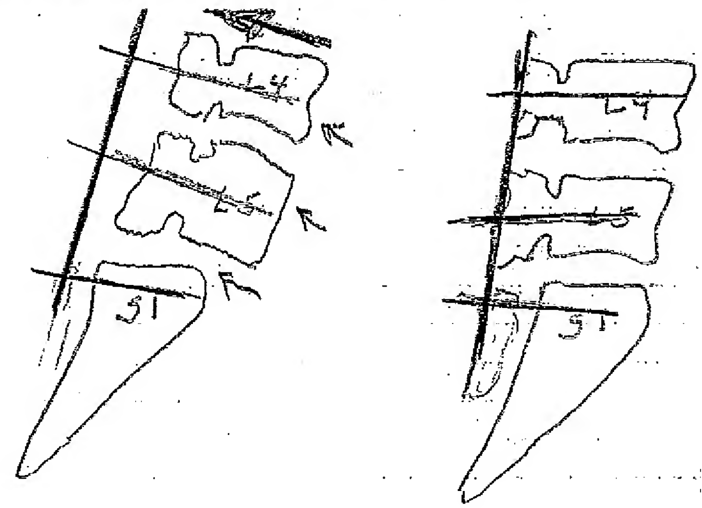


Pre-op A/P



Lateral View of Construct

2.) Spondylolisthesis – correction (needed for more severe slips – e.g., Grade 3) via pulling vertebrae up to rod.



Obviously, a flexible cable between segments (Graf, Dynesys) provide no such capability.

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Exhibit B

E

Fatigue Resistance – Some Considerations

- Consider fatigue limit of material/design
  - <u>Material</u> – more fatigue resistant Ti ?
  - <u>Design</u> – radii and K_{IC} values ?
  - <u>Manufacture</u> – surface roughness, treatment, prestress…

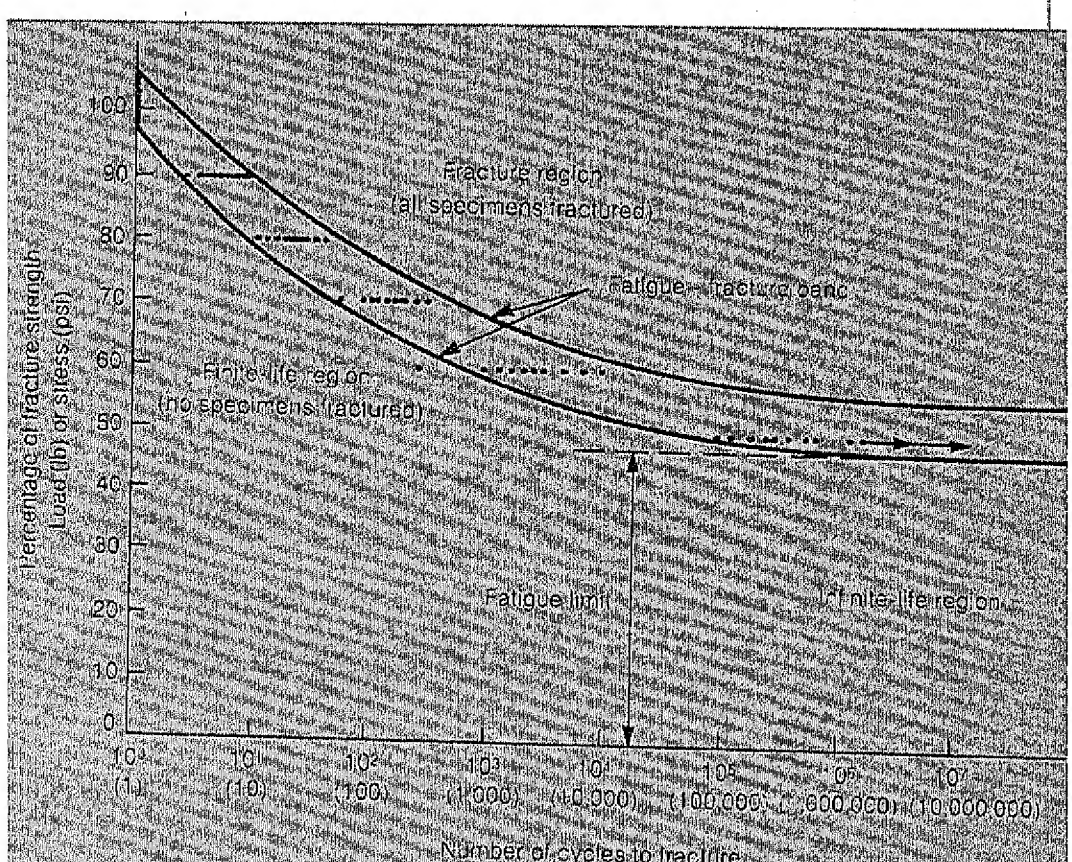


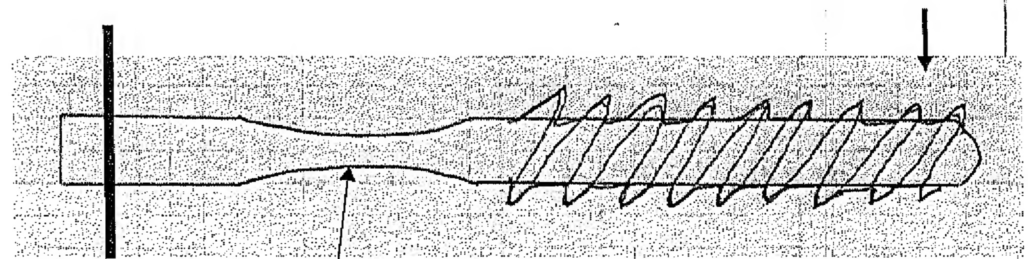
Fig. 11. Typical fatigue (S-N) diagram of laboratory fatigue testing of medium-strength ferrous metal. See text.

F

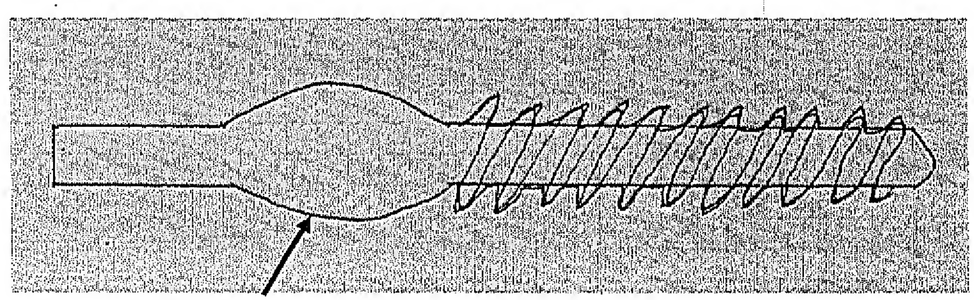
Fatigue Considerations – Screw Design

- One possibility –
  - maintain material cross-section volume via increasing lateral width at flexion point
- Additional advantage –
  - assures that flexion point is extra-pedicular
- Allow uniform material
  - 510(k) more likely?

Lateral View



Top View



Incr x-section as lateral x-section decreases

n juvenile scoliosis

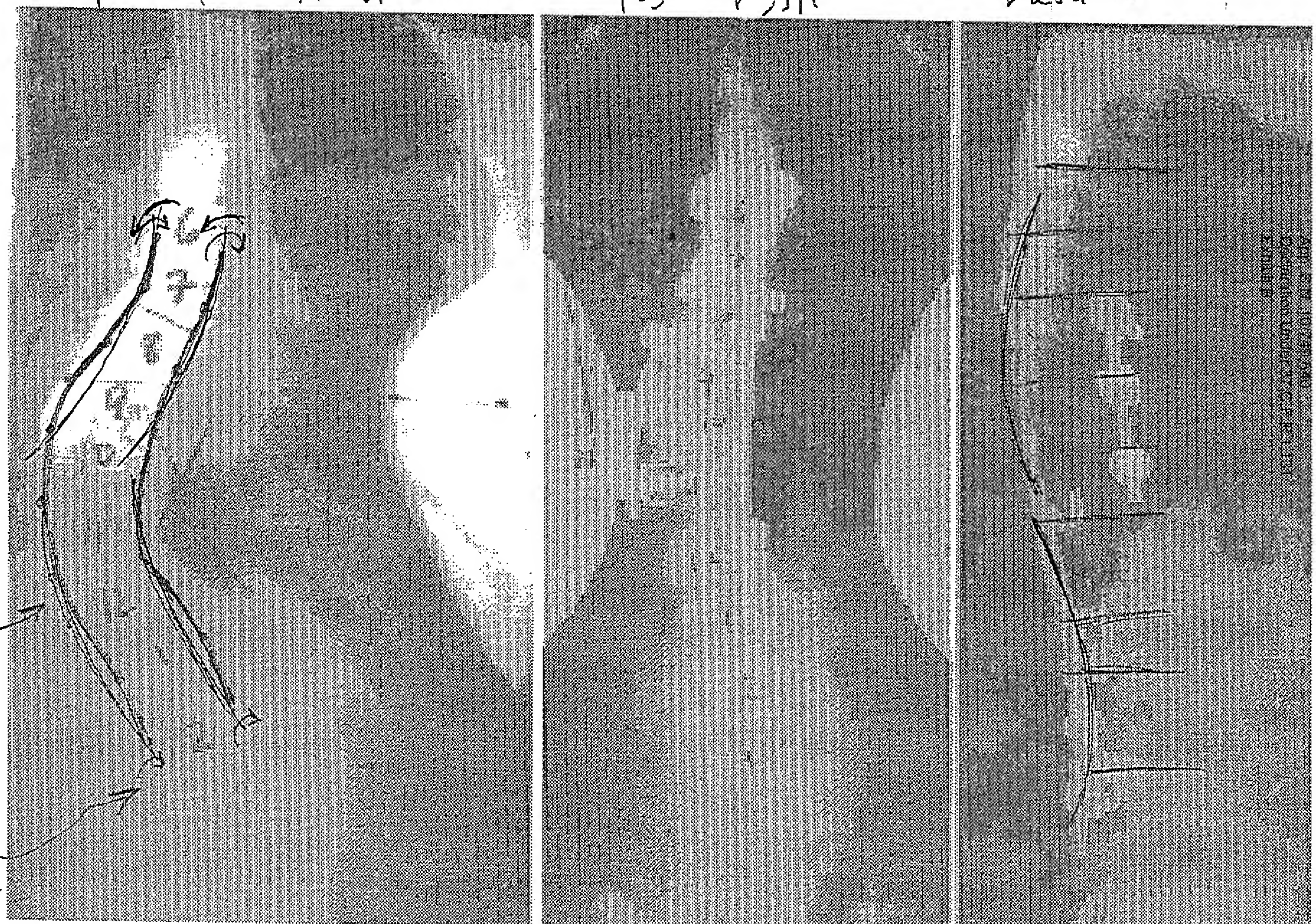
G

rod
ation
ane
gital
ys

Pre-op A/P view

Post-op A/P

Lateral



1.) place rod and contour as shown.

2.) Rotate and reduce

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Exhibit B

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Exhibit B

Michael D. Beck

From: Robert M. Rodrick [RRodrick@spinewave.com]
Sent: Wednesday, AM
To: Michael D. Beck
Subject: FW: FW: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Mike

I'll call you re this email.

Bob

-----Original Message-----
From: Larry Boyd [mailto:lmb13@acpub.duke.edu]
Sent: Wednesday, 0 AM
To: Robert M. Rodrick
Subject: RE: FW: SW-0005 DYNAMIC SPINAL STABILIZATION SYSTEM

Bob,
The FAX should be coming across now. Here are some points I think should be clear from the FAX.

1. Fatigue resistance will be important. Many of these issues can be partially addressed with material selection, proper machining and metal finishing of the sensitive screw surface.

2. Fatigue resistance may be an issue with a flexible screw with reduced cross section. In order to maintain cross sectional area for fatigue considerations, it may be possible to increase the cross section in one plane to offset the decrease in the other plane. An additional advantage of this increased cross section is that it would prevent the surgeon from inserting the flexible portion into the pedicle so that the flexion point remains extrapedicular.

3. DyNeSys has been promoting an advantage of their system over interspinous systems (like DIAM) as its location of center of rotation vs. the normal plane of motion of the spine. The normal rotation location for the spine is in the posterior 1/3 of the disc space as shown in the figure. That said, our concept is even closer to that location than Dynesys or other intersegmental concepts.

4. One additional thought. Spinal fixation procedures performed for correction of deformity in young patients could be problematic over time due to unloading of their discs for long periods of time. It would be advantageous to use a dynamic fixation concept for such procedures. However, if the flexible segments are between vertebrae (like Dynesys), it will be difficult to maintain correction, especially in multiple planes (coronal and sagittal). With our concept, a rigid rod can be used to rotate and correct the spine in 3-dimensions (as is currently done), while allowing for some physiologic loading of the disc spaces over the long periods of time likely in these very young patients. Of course, fatigue issues will be important. But, staying below the fatigue limits for the system should be possible with design considerations and material optimization.

Hope this helps. See you next week. Regards, Larry.

Larry

Spine Wave, Inc.

Two Enterprise Dr., Suite 302
Shelton, CT 06484
Tel: (203) 944-9494
Fax: (203) 944-9493

RECEIVED

Facsimile Transmittal

To:	Mike Beck	**Fax:**	317-638-2139
From:	Robert Rodrick	**Date:**	
RE:	Attachment	**Pages:**	4

Mike:

Please see attached regarding our discussion concerning the SW 005 draft.

Regards,

Robert Rodrick

App. S.N. 10/749,640
Declaration Under 37 C.F.R.1.131
Exhibit B

Spine Wave, Inc.

Two Enterprise Drive
Suite 302
Shelton, CT 06484

Phone: 203-944-9494
Fax: 203-944-9493

Mr. Mike Beck
Maginot, Moore & Bowman LLP
Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, IN 46204-5115

Re: Invention SW005

Dear Mike:

Enclosed are copies of materials related to SW005.

Call to discuss.

Very truly yours,

Robert M. Rodrick/cln

Robert M. Rodrick
Chief Patent Counsel

RMR/cln
Enclosures